

# Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers

KATRIEN VANDERWEE, MARIA H. F. GRYPDONCK, TOM DEFLOOR

Nursing Science, Department of Public Health, Ghent University, UZ 2 Blok A, De Pintelaan 185, B 9000 Gent, Belgium

Address correspondence to: K. Vanderwee. Fax: (+32) 9 240 50 02. Email: katrien.vanderwee@ugent.be

## Abstract

**Background:** studies of the effectiveness of alternating pressure air mattresses (APAMs) for the prevention of pressure ulcers are scarce and in conflict.

**Objective:** evaluating whether an APAM is more or equally effective as the standard prevention.

**Design:** randomised controlled trial.

**Setting and subjects:** patients admitted to 19 surgical, internal, or geriatric wards in seven Belgian hospitals were included if they were in need of prevention of pressure ulcers. To define this need, two methods were used randomly: the Braden Scale or the presence of non-blanchable erythema (NBE).

**Methods:** 447 patients were randomised into either an experimental or a control group. In the experimental group, 222 patients were lying on an APAM (Alpha-X-Cell<sup>®</sup>, Huntleigh Healthcare, UK). In the control group, 225 patients were lying on a visco-elastic foam mattress (Tempur<sup>®</sup>, Tempur-World Inc., USA) in combination with turning every 4 hours. Both groups had identical sitting protocols.

**Results:** there was no significant difference in incidence of pressure ulcers (grade 2–4) between the experimental (15.6%) and control group (15.3%) ( $P=1$ ). There were significantly more heel pressure ulcers in the control group ( $P=0.006$ ). There was an interaction effect between the risk assessment method and preventive measures for the development of all pressure ulcers and sacral pressure ulcers.

**Conclusion:** fewer patients developed heel pressure ulcers on an APAM. Patients identified as being in need of prevention based on the presence of NBE had a tendency to develop fewer pressure ulcers on an APAM. Patients identified as being in need of prevention, based on the Braden Scale, appeared to develop more sacral pressure ulcers on an APAM.

**Keywords:** *decubitus ulcer, prevention and control, randomised controlled trial, beds, elderly*

## Introduction

Pressure ulcers are serious complications of hospitalisation that need to be prevented whenever possible. A pressure ulcer is an area of localised damage to the skin and the underlying tissue caused by pressure and shearing forces [1]. Effective preventive measures reduce the intensity and/or the duration of pressure and shearing forces. Pressure-relieving mattresses, cushions and postures reduce the intensity of pressure and shearing forces [2]. APAMs and repositioning reduce the duration of pressure and shearing forces [3]. APAMs generate alternating high and low interface pressure between the body and support, by alternating inflation and deflation of air-filled cells [4].

APAMs have not been studied intensively. Using an extended PubMed (1965–2004) search, 16 studies were identified. Eight randomised controlled trials (RCTs) were relevant to the subject of this study. Five studies reported

no statistical difference in the effectiveness of APAMs and various constant low-pressure devices [5–9]. In the other RCTs, a significant difference was observed [10–12]. The relative benefits of alternating pressure and constant low-pressure devices are unclear [4, 13].

Besides APAMs, repositioning is another commonly used strategy to reduce the duration of pressure and shearing forces. Although repositioning is generally accepted, there is scant evidence in the literature regarding the effectiveness of turning. Turning every 4 hours on a visco-elastic foam mattress (in combination with pressure-reducing positions) is recommended by the Belgian and Dutch pressure ulcer guidelines [14, 15].

The aim of this study was to determine whether an APAM is more or equally effective than standard prevention. An RCT in an acute care setting was considered the most appropriate design to assess the effectiveness of an APAM in preventing pressure ulcers.

## Methods

### Subjects and recruitment

The RCT was carried out between May 2000 and August 2002 in 19 surgical, internal medicine, and geriatric wards in seven Belgian hospitals. Each nursing ward took part in the study for 20 weeks. Inclusion criteria were: > 18 years, expected hospitalisation stay at least 3 days, no grade 2, 3, or 4 pressure ulcer lesions [16] on admission, body weight < 140 kg, and no contraindication for turning due to medical reasons. None of the included patients had scars of previous pressure ulcer lesions. Patients were included if they were considered in need of preventive measures. To define this need, two methods were randomly used. The patient's risk status was defined using either the Braden Scale [17] or the presence of a grade 1 pressure ulcer (non-blanchable erythema or NBE). The Braden Scale defines whether a patient is at risk of developing pressure ulcers. The scale consists of six subscales: sensory perception, moisture, activity, mobility, nutrition, and friction and shear. The total score ranges from 6 to 23 [17]. Patients with a Braden Scale score < 17 were considered at risk [1, 14, 15]. The predictive validity of this scale has been tested in several studies [18, 19]. Preventive measures were started on other patients based on the presence of NBE [14, 15, 20]. These two methods were applied, since both are commonly used in clinical practice and are recommended by the Belgian Pressure Ulcer Guidelines [14].

Approval for this study was granted by the ethics committee of Ghent University Hospital and of each participating hospital.

### Intervention

In the experimental group, patients were lying on an alternating pressure overlay (Alpha-X-Cell<sup>®</sup>, Huntleigh Healthcare, UK). No turning protocol was used. Since the principle of an APAM is to alternate the pressure points on the patient [3], theoretically, repositioning is not necessary. In the control group, a standardised prevention protocol was used. Patients were lying on a visco-elastic polyethylene-urethane foam mattress (Tempur<sup>®</sup>, Tempur-World Inc., USA) in combination with a standardised turning protocol every 4 hours. The following sequence of position changing was used: semi-Fowler 30°, right-side lateral position 30°, semi-Fowler 30°, left-side lateral position 30° [2]. In both groups the heels of the patients were elevated from the mattress by placing an ordinary cushion beneath the lower legs [1, 14, 21]. The sitting protocol was standardised and identical in both groups. When patients were seated in a chair, an air cushion (Airtech<sup>®</sup>, Huntleigh Healthcare, UK) was used for all patients. They were also asked to stand up every 2 hours, alone or with help. If the back of the chair could be tilted backwards, the patient's legs were put on a footrest. If the back of the chair could not be adjusted, the patient's feet were placed on the floor [22].

Based on a 12% incidence of pressure ulcers (grade 2 or higher) in hospitals, a sample size was calculated of 223 patients (in each group) to detect a difference of 7% in the

incidence of pressure ulcers between the experimental and control group ( $\alpha=0.05$ ; power=80%).

### Data collection

The occurrence of pressure ulcers was assessed daily by ward nurses. An additional daily inspection of the skin by a researcher was felt to be an unnecessary burden for patients. A random sample of patients was observed at unexpected moments by both the researcher and the data nurse. Pressure ulcers were classified according to the four grades of the European Pressure Ulcer Advisory Panel (EPUAP) [16]. In order to standardise distinguishing between blanchable and non-blanchable erythema, a 4 cm × 4 cm transparent pressure disk was used. The nurse pressed the transparent disk on the erythema. If the erythema blanched, it was defined as blanchable erythema. If the erythema remained while pressing, it was defined as NBE [23, 24]. In addition, a Braden score was obtained for all patients on admission and every 3 days thereafter [17].

A data nurse was responsible for the follow-up of the study on each ward. Once a week, the nurse scored the skin condition and the Braden Scale of a randomly selected sample of patients. This was carried out unannounced and independently of the other nursing staff. The researcher carried out similar observations independently once a week. The inter-rater reliability for the classification of pressure ulcers between researcher, nursing staff, and data nurse ranged from  $\kappa=0.88$  (95% CI 0.78–0.97) to  $\kappa=0.94$  (95% CI 0.91–0.97). The inter-rater reliability for scores on the Braden Scale was also high. Kappa varied from 0.78 (95% CI 0.74–0.82) to 0.87 (95% CI 0.82–0.95).

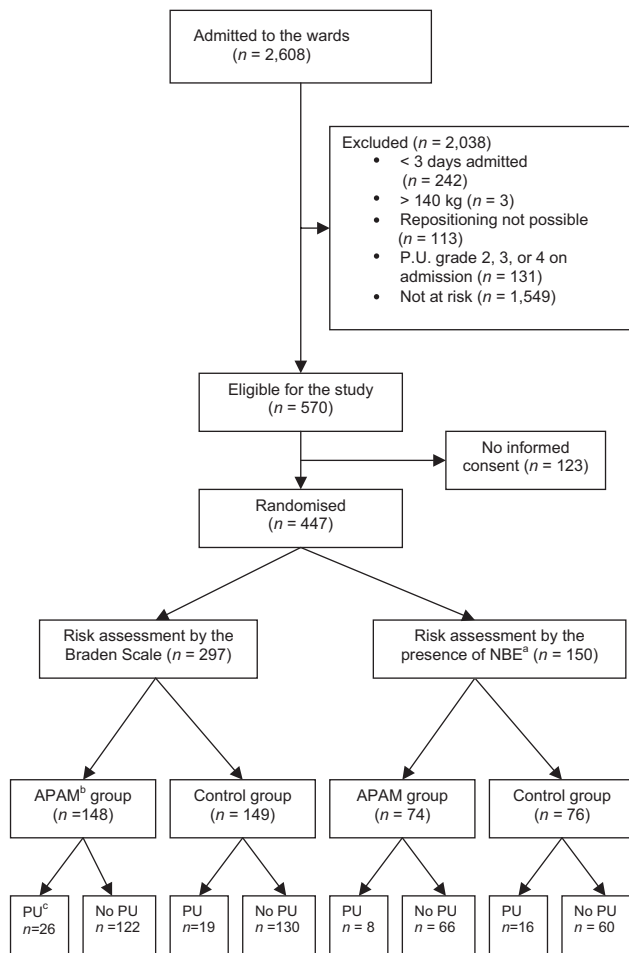
### Statistical analysis

The sequence of allocation to the experimental or control group was determined beforehand based on randomisation tables generated with the SPSS 10 software package [25]. Serially numbered, closed envelopes were made for each participating ward. The envelope with the lowest number was opened upon admission of a new patient.

The Mann–Whitney U test was used for continuous variables that were not normally distributed and for categorical variables. Fisher's exact test, and the  $\chi^2$  test were used for categorical variables. A logistic regression analysis and Kaplan–Meier survival analysis were performed to evaluate the effect of the prevention protocol on the incidence of pressure ulcers (grade 2 or higher) [19, 26]. All analyses were done with the SPSS 10 software package [25]. A value of  $P < 0.05$  was considered statistically significant.

## Results

Of the 2,608 patients who were admitted to the participating wards during the study period, 570 met the inclusion criteria, of whom 123 patients gave no informed consent. In total, 447 patients were included in the study (Figure 1). The median age was 82 years (interquartile range 77–88 years), 93% of the patients were older than 65 years and 30% were older than 85 years. None of the patients had a dark skin. Random allocation of the 447 patients admitted to the study resulted in 222 patients in the experimental group (APAM)



**Figure 1.** Flow of patients through the trial. <sup>a</sup>NBE, non-blanchable erythema; <sup>b</sup>APAM, alternating pressure air mattress; <sup>c</sup>PU, pressure ulcer.

and 225 patients in the control group, respectively (Figure 1). Table 1 shows the baseline characteristics of the APAM and control groups. Since the groups were similar in all characteristics except for medical speciality, this variable is adjusted for in the analysis.

In the APAM group, 34 (15.3%) patients developed a pressure ulcer (grade 2–4). That figure was 35 patients (15.6%) in the control group. The incidence rate was 1.46 (34/2,371 days) (95% CI 0.98–1.97) in the APAM group and 1.66 (35/2,106 days) (95% CI 1.11–2.21) in the control group. Univariate analysis showed no difference in the incidence of pressure ulcers (grade 2–4) between the APAM and control group ( $P=1$ , Fisher's exact test). Using a logistic regression analysis, the effect of the prevention protocols on the incidence of pressure ulcers (grade 2–4) was evaluated, adjusting for four variables: length of stay, medical speciality, risk assessment method, and learning effect (Table 2). The learning effect of the nursing staff in executing the prevention protocol was studied by comparing the first 10 weeks that a ward participated in the study and the last 10 weeks. There was a statistically significant interaction

effect between risk assessment method and prevention protocol (Wald  $\chi^2=5.25$ ;  $df=1$ ;  $P=0.02$ ). Therefore, a separate logistic regression analysis was performed for the Braden group (patients identified as being in need of preventive measures based on the Braden Scale) and the NBE group (patients identified as being in need of prevention based on the presence of NBE). These logistic regression analyses revealed no significant difference between the APAM group and the control group in the occurrence of grade 2–4 pressure ulcers (Table 2).

To eliminate the possible influence of sitting, despite the standardised sitting protocol, a logistic regression was performed including only bed-bound patients ( $n=149$ ). There was no interaction effect between the risk assessment method and the prevention protocol. The incidence of pressure ulcers was not different between the APAM group and the control group (Wald  $\chi^2=0.688$ ;  $df=1$ ;  $P=0.41$ ).

A significant difference was found in the location of pressure ulcers between the two groups ( $P=0.003$ ; Fisher's exact test). In the APAM group, 25 patients (73.5%) had a pressure ulcer on the sacrum, five (14.7%) on the heels, and four (11.8%) on another location. In the control group, 19 patients (54.3%) had a pressure ulcer on the sacrum and 16 (45.7%) on the heels. A separate Fisher's exact test for each location revealed only statistical significance for the heels ( $P=0.008$ ; Fisher's exact test). A logistic regression was performed with heel pressure ulcers as outcome to adjust for length of stay, medical speciality, risk assessment method, and prevention protocol variables. There was no interaction between risk assessment method and prevention protocol. In the APAM group, significantly fewer patients developed a heel pressure ulcer compared to the control group (Wald  $\chi^2=7.533$ ;  $df=1$ ;  $P=0.006$ ).

The same logistic regression analysis was performed that included only patients with sacral pressure ulcers. There was a statistically significant interaction effect between risk assessment method and prevention protocol (Wald  $\chi^2=5.675$ ;  $df=1$ ;  $P=0.02$ ). Patients identified as being in need of preventive measures based on the Braden Scale tend to develop more sacral pressure ulcers on an APAM than on a visco-elastic mattress (OR 2.77, 95% CI 1.00–7.69). The difference approached significance ( $P=0.05$ ). The separate logistic regression analysis for the NBE group revealed no significant difference ( $P=0.34$ ).

There was a significant difference in severity of pressure ulcers between the two groups (Wald  $\chi^2=4.503$ ;  $df=1$ ;  $P=0.034$ ). Of the patients with pressure ulcers, in the APAM group 26 (76.5%) patients developed a grade 2 pressure ulcer and eight (23.5%) patients developed a grade 3 or 4 pressure ulcer. In the control group, 33 (94.3%) patients developed a grade 2 pressure ulcer and two (5.7%) a grade 3 or 4 pressure ulcer. In the subgroups the difference was not significant.

Using a Kaplan–Meier survival analysis, the time to develop a pressure ulcer was analysed between patients lying on an APAM and patients lying on a visco-elastic mattress. There was no significant difference between the two prevention protocols (log rank test=0.021,  $df=1$ ,  $P=0.65$ ). Adjusted for the risk assessment protocols, survival analysis also revealed no significant difference (log rank test=0.02,  $df=1$ ,  $P=0.66$ ).

**Table 1.** Baseline characteristics of patients recruited. Values are medians (interquartile range) unless stated otherwise

	Braden group ( <i>n</i> = 297)			NBE <sup>b</sup> group ( <i>n</i> = 150)					
	APAM <sup>a</sup> group ( <i>n</i> = 222)	Control group ( <i>n</i> = 225)	<i>P</i> value	APAM group ( <i>n</i> = 148)	Control group ( <i>n</i> = 149)	<i>P</i> value	APAM group ( <i>n</i> = 74)	Control group ( <i>n</i> = 76)	<i>P</i> value
Age (years)	81 (76–88)	82 (78–87)	0.66 <sup>c</sup>	81 (75–87)	82 (77–86)	0.6 <sup>c</sup>	83 (78–89)	83 (78–89)	0.89 <sup>c</sup>
Length of stay in hospital (days)	22 (11–39)	18 (11–31.5)	0.11 <sup>c</sup>	22 (11–40.25)	17 (10–30)	0.07 <sup>c</sup>	21 (11–37)	21 (12–35)	0.85 <sup>c</sup>
Mean Braden score (SD) on admission	14.6 (3.06)	14.2 (2.93)	0.13 <sup>d</sup>	14.5 (2.82)	14.3 (2.69)	0.39 <sup>d</sup>	14.8 (3.5)	14.1 (3.38)	0.2 <sup>d</sup>
Gender %			0.31 <sup>e</sup>			0.7 <sup>e</sup>			0.39 <sup>e</sup>
Female	60.6	65.6		66.4	69.3		49.3	58	
Medical speciality %			0.02 <sup>f</sup>			0.13 <sup>f</sup>			0.11 <sup>f</sup>
Surgery	6.8	2.2		6.8	2.7		6.8	1.3	
Internal	31.1	25.3		31.8	26.8		29.7	22.4	
Geriatrics	62.2	72.4		61.5	70.5		63.5	76.3	
Primary medical diagnosis %			0.22 <sup>f</sup>			0.59 <sup>f</sup>			0.29 <sup>f</sup>
Cardiovascular and respiratory problems	23	31.2		22.4	28.9		24.2	35.8	
Gastro-enteric problems	13.4	14.9		15.2	14.8		9.7	14.9	
Orthopaedic and neurological problems and revalidation	33.7	30.7		32	31.9		37.1	28.4	
Psychiatric and social problems and others	29.9	23.3		30.4	24.4		29	20.9	

<sup>a</sup>APAM, alternating pressure air mattress; <sup>b</sup>NBE, non-blanchable erythema; <sup>c</sup>Mann–Whitney U test; <sup>d</sup>Student's *t*-test; <sup>e</sup>Fisher's exact test; <sup>f</sup> $\chi^2$  test.

**Table 2.** Binary logistic regression with pressure ulcers as dependent variable and risk factors as independent variables

	Total group (n = 447)						Braden group (n = 297)						NBE <sup>b</sup> group (n = 150)					
	N	B <sup>f</sup> (SE) <sup>g</sup>	P	OR (95% CI)	N	B (SE)	P	OR (95% CI)	N	B (SE)	P	OR (95% CI)	N	B (SE)	P	OR (95% CI)		
<b>All pressure ulcers</b>	69	0.007 (0.004)	0.05	1.01 (1.00–1.02)	45	0.02 (0.01)	0.003	1.02 (1.01–1.03)	24	0.00 (0.01)	0.97	1.00 (0.99–1.01)						
Length of stay			0.05								0.06							
Medical speciality <sup>a</sup>			0.34	1.8 (0.54–6.07)		1.03 (0.69)	0.13	2.81 (0.73–0.77)		-5.16 (18.34)	0.78	0.01 (0.00–2.33 <sup>E+13</sup> )						
Surgery		-0.88 (0.41)	0.03	0.41 (0.19–0.92)		-0.80 (0.52)	0.13	0.45 (0.16–1.26)		-0.77 (0.67)	0.25	0.46 (1.24–1.73)						
Internal medicine		0.32 (0.35)	0.37	1.37 (0.69–2.75)	26	0.23 (0.37)	0.54	1.25 (0.61–2.57)	8	-0.92 (0.52)	0.08	0.40 (0.14–1.11)						
Prevention (APAM) <sup>b</sup>		0.60 (0.39)	0.13	1.82 (0.84–3.93)		-	-	-		-	-	-						
Risk assessment method (NBE) <sup>c</sup>		0.23 (0.29)	0.41	1.26 (0.72–2.22)		0.29 (0.36)	0.43	1.34 (0.66–2.72)		0.04 (0.50)	0.93	1.04 (0.39–2.75)						
Learning effect (Second half) <sup>d</sup>		-1.46 (0.64)	0.02	0.23 (0.07–0.81)		-	-	-		-	-	-						
Interaction Prevention and risk assessment method																		
<b>Sacral pressure ulcers</b>	44	0.004 (0.004)	0.34	1.00 (1.00–1.01)	25	0.02 (0.01)	0.02	1.02 (1.00–1.03)	19	-0.003 (0.008)	0.70	1.00 (1.00–1.01)						
Length of stay			0.03								0.40							
Medical speciality <sup>a</sup>		0.57 (0.69)	0.41	1.76 (0.45–6.83)		1.04 (0.76)	0.17	2.82 (0.64–2.47)		-6.17 (30.22)	0.84	0.002 (0.00–1.10 <sup>E+23</sup> )						
Surgery		-1.52 (0.63)	0.02	0.22 (0.07–0.75)		-1.90 (1.06)	0.07	0.15 (0.02–1.19)		-1.05 (0.79)	0.18	0.45 (0.74–1.64)						
Internal medicine		1.03 (0.51)	0.03	2.98 (1.1–8.08)	18	1.02 (0.52)	0.05	2.77 (1.00–7.69)	7	-0.52 (0.55)	0.34	0.60 (0.20–1.73)						
Prevention (APAM) <sup>b</sup>		1.42 (0.54)	0.008	4.12 (1.44–1.82)		-	-	-		-	-	-						
Risk assessment method (NBE) <sup>c</sup>		-1.78 (0.75)	0.02	0.17 (0.04–0.73)		-	-	-		-	-	-						
Interaction Prevention and risk assessment method																		
<b>Heel pressure ulcers</b>	21	0.009 (0.006)	0.12	1.01 (1.00–1.02)	16	0.01 (0.01)	0.17	1.01 (0.10–1.03)	5	0.01 (0.01)	0.41	1.01 (0.99–1.04)						
Length of stay			0.68								0.95							
Medical speciality <sup>a</sup>		0.95 (1.14)	0.41	2.57 (0.28–3.79)		0.96 (1.14)	0.40	2.62 (0.28–4.53)		0.7 (229.50)	1.00	1.45 (0.00–3.26 <sup>E+195</sup> )						
Surgery		-0.11 (0.60)	0.86	0.90 (0.28–2.91)		-0.18 (0.69)	0.79	0.83 (0.21–3.25)		0.39 (1.24)	0.76	1.47 (0.13–16.67)						
Internal medicine		-1.83 (0.67)	0.006	0.16 (0.04–0.59)	4	-1.52 (0.68)	0.03	0.22 (0.06–0.83)	1	-9.73 (53.94)	0.86	0.00 (0.00– <sup>i</sup> )						
Prevention (APAM) <sup>b</sup>		-0.75 (0.60)	0.21	0.47 (0.15–1.52)		-	-	-		-	-	-						
Risk assessment method (NBE) <sup>c</sup>																		

<sup>a</sup>Reference category is geriatrics, <sup>b</sup>reference category is visco-elastic foam mattress in combination with 4 hourly turning, <sup>c</sup>reference category is Braden Scale, <sup>d</sup>reference category is first half, <sup>e</sup>no interaction between risk assessment method and prevention protocol, <sup>f</sup>B = regression coefficient, <sup>g</sup>SE = standard error, <sup>h</sup>NBE = non-blanchable erythema, <sup>i</sup>No interval estimation due to too few data.

## Discussion

Despite a strict execution of recommended preventive measures, a substantial percentage (15.4%) of the patients identified as being at risk developed a pressure ulcer. The overall incidence of pressure ulcers was 2.6% ( $n=69/2,608$ ).

In the present study, the incidence of pressure ulcers was comparable in patients nursed on an APAM and those nursed on a visco-elastic mattress in combination with turning every 4 hours. This finding accords with previous studies on APAMs and constant low-pressure devices [5–9]. However, patients in the APAM group seemed to develop more severe pressure ulcers than those in the control group. Due to the limited numbers of patients, we must be careful in generalising this finding.

Remarkably, there was an interaction effect between the prevention protocol and the risk assessment method. Caution is required in interpreting the results of the subgroups. If the data are split up into the Braden and NBE groups, the numbers of patients become too small. Therefore, we can only discover tendencies. Patients identified as being in need of prevention based on the presence of NBE had a tendency to develop fewer pressure ulcers on an APAM ( $n=8$ , 10.8%) than on a visco-elastic mattress in combination with turning every 4 hours ( $n=16$ , 21.1%). However, this result was not statistically different. In the Braden group, the difference was not significant.

Considering the sacral pressure ulcers, we also observed an interaction effect between the prevention protocol and the risk assessment method. In the Braden group, a possible hypothesis for the slight tendency of more sacral pressure ulcers on an APAM is that the pressure on the sacrum cannot be completely relieved by an APAM. A constant low pressure remains on the sacrum. The literature provides evidence that constant low pressure is more damaging for the tissue than alternating pressure [27]. If there is a constant (low) pressure, repositioning on an APAM is required. Another hypothesis is that continued inflation and deflation of the cells of an APAM produces shearing forces. It is known that shearing forces increase the risk for developing pressure ulcers [13].

There were significantly less heel pressure ulcers in the APAM group (14.7%) than in the control group (45.7%). The percentage in the control group is consistent with other studies reporting anatomical locations [28, 29]. However, contrary to the present study, in those studies heels were not elevated from the mattress. The percentage in the APAM group was notably lower, but is still high considering that the heels were elevated from the mattress. One can question whether the heels were elevated from the mattress in the correct way. Some patients pushed away the cushion beneath their legs. Other patients turned up their legs and thus their heels were lying on the cushion. In the APAM group, when patients pushed away the cushion, their heels fell between the cells of the mattress and were pressure free.

For ethical reasons, the duration of sitting was not standardised. The sitting protocol was standardised. We found no significant difference in the analyses with or without mobile and chair-bound patients.

In conclusion, patients nursed on an APAM seemed to develop more severe pressure ulcers. Fewer patients developed heel pressure ulcers on an APAM. Patients identified as being in need of preventive measures based on the presence of NBE had a tendency to develop less pressure ulcers on an APAM than on a visco-elastic mattress in combination with 4-hourly turning. Patients identified as being in need of prevention based on the Braden Scale appeared to develop more sacral pressure ulcers on an APAM.

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## Key points

- Fewer patients developed heel pressure ulcers on an APAM.
  - Patients seemed to develop more severe pressure ulcers on an APAM.
  - Patients identified as being in need of preventive measures based on the presence of NBE had a tendency to develop less pressure ulcers on an APAM than on a visco-elastic mattress in combination with 4 hourly turning.
  - Patients identified as being in need of prevention based on the Braden Scale appeared to develop more sacral pressure ulcers on an APAM than on a visco-elastic mattress in combination with 4 hourly turning.
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## Conflicts of interest declaration

There are no conflicts of interest.

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